

NEPA Decision Worksheet

Permit #
 Institution
 Organism
 Category
 Gene

05-293-01r
 Ventria Bioscience
 Rice
 Pharmaceutical proteins produced
 Serum albumin

1. Confinement	
Confinement and mitigation conditions have been reviewed and determined to be adequate	X
2. Threatened or Endangered Species or its habitat	
Resident or migratory in counties and harm to threatened or endangered species or habitat is likely	
Resident or migratory in counties and harm to threatened or endangered species is unlikely	X
None observed in area (no harm to threatened and endangered species)	
New or Novel	
3. New or Novel Crop	
Never used in a field trial	
Not new but no prior EA	
Not new and prior EA	X
4. New or Novel Trait (gene product)	
Never used in a field trial	
Not new but no prior EA	
Not new and prior EA	X
Raises new issues	
5. Cumulative Effects	
Cumulative effects likely	
Cumulative effects possible	
Cumulative effects unlikely	X
6. Plant Pollination	
Primarily bee or insect pollinated crop	
Primarily wind pollinated food or feed crop	
Primarily self fertilized food or feed crop	X
Non-food or feed crop	
7. Effects on Food/Feed Supply	
Known allergen, antinutritive, oral toxicant	
Food safety not established	X
GRAS status or approved food additive for native protein	
GRAS status or approved food additive for plant produced protein	
8. Isolation Distance	
AOSCA standard for crop	10 feet
Proposed isolation distance	1320 feet
9. Scale	
>100 acres/trait/crop/institution/year	
50-99 acres/trait/crop/institution/year	
10-49 acres/trait/crop/institution/year	X
<10 acres/trait/crop/institution/year	
10. Effects (positive or negative) on other species	
Significant effects expected/observed	
Minimal, non-cumulative effects expected/observed	
No effects expected/observed	X
11. Sexually Compatible Relatives	
Relatives within dispersal distance	
Relatives not within dispersal distance	X
12. Seed Dormancy	
>3 years	
3 years	
2 years	
<2 years	X
13. Persistence in environment	
Crop can naturalize	
Crop can persist 3-5 years without human intervention	
Crop does not persist without intervention	X
14. Comments	
4. Previous EA for human serum albumin in rice for permit 96-355-01r	

Additional supportin documentation is found in the summary risk assessment completed on

January 18, 2006

NEPA Decision Summary for Permit 05-293-01r

Based on a review of Permit 05-293-01r, the following determinations were made:

- Two threatened or endangered animal species exist or once existed in Washington County. None of the species listed inhabits rice fields and do not consume rice so would not be expected to be impacted by this field test. Therefore these field trials will not harm or have adverse or other significant effects on threatened or endangered species.
- Hundreds of field trials have been performed with transgenic rice plants under APHIS authority, and APHIS is familiar with rice biology and methods to manage confined rice field trials. Ventria previously grew rice in this same location in North Carolina in 2005 and satisfactorily maintained a confined field test.
- Rice is highly self-pollinated, and is not generally pollinated by insects. Association of Official Seed Certifying Agencies (AOSCA) certified seed regulations for foundation seed and rice seed certification standards require a minimum isolation distance from other rice varieties of at least ten feet when hand- or machine-planted. A 50 foot fallow zone and a separation distance of 1320 feet from any other rice (one hundred thirty two times the AOSCA standard) as proposed by the applicant should be more than adequate to prevent unintended release of the transgenic rice into adjacent fields. This distance between these rice fields and any potential commercial fields or research plots is sufficient to prevent outcrossing.
- Because all transgenic plant material will be removed from the test site and destroyed, there will be no foreseeable cumulative impacts resulting from field trials of these transgenic lines. Ventria monitored for the presence of lactoferrin in the surrounding soil during the 2005 growing season and none was found. Nonetheless Ventria will continue to monitor for cumulative effects in this planting.
- Human serum albumin is a soluble, monomeric protein which comprises about one-half of the blood serum protein. It is used in medical practice to replace blood volume in burn victims, patients suffering acute traumatic shock and those undergoing certain types of surgery. It has no known toxic properties. It has no reported oral or dermal activities.
- In previous field tests and applications, seed dormancy in rice has not been observed.
- There is no weedy red rice in the immediate area since rice has not been grown in the area in the past. Ventria scouted for weedy rice during and following the 2005 planting and none was found. The applicants will be required to scout for and removed any weedy rice that is found within the nursery plots and within the 1320 isolation zone.

For the above reasons, APHIS has determined that (1) pursuant to 7 C.F.R. 372, the field trials proposed under permit #05-293-01r will not significantly affect the physical environment and (2) there are no applicable, extraordinary, or other reasonably foreseeable circumstances under which significant environmental effects could occur given the protective and ameliorative measures specified above. Therefore, this field test is deemed confined within the meaning of 7 C.F.R. § 372.5.

Signed: _____ /s/
Neil E. Hoffman
Director, Environmental Risk Analysis Division

Date: _____ 1.23, 2006